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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Abbott Laboratories, et al.,	)	
Plaintiff,	)	**01 C 1867**
v.	)	**Judge Ronald A. Guzmán**
Baxter Pharmaceutical Products, Inc., et al.	)	
Defendants.	)	

AMENDED BENCH OPINION

This case involves U.S. Patent Number 5,990,176 (the "'176 Patent" or "Patent"), which claims compositions and methods of preventing the degradation of a widely used anesthetic, sevoflurane, by adding an effective or sufficient amount of certain specific Lewis acid inhibitors, one of which is water.[1] Water is used in the production of sevoflurane, and so there is nothing novel about having a combination of the two. In fact, because sevoflurane naturally absorbs water and there is always some humidity in the atmosphere, it is practically impossible to produce completely dry sevoflurane.

[1]The '176 Patent uses these terms, "effective" and "sufficient," interchangeably and so will the Court. (Tr. 235, Dr. Jung.)

FACTS

Ironically, sevoflurane was invented by Baxter scientists. (Tr. at 1478, Dr. Lessor.) The original compound patent for sevoflurane was applied for and granted in the 1970s. (*Id.* at 1476-77, Dr. Lessor; DX 46.) The original patent expired in 1989. (Tr. 1478, Dr. Lessor.)

Sevoflurane is a useful anesthetic because it has a sweet smell and is a drug that acts and wears off quickly:

> Sevoflurane was a very fast-acting drug. You could put it on a mask, have a patient breathe into it. It had a very sweet smell; it wasn't a pungent odor. Many of the other inhalation agents are difficult for a patient to breathe in. So it made it particularly useful to use in pediatrics, which, you know, masking a child into anesthesia when they're frightened and combative. Oftentimes you don't have an intravenous line to get an anesthetic in, so that was a very compelling attribute of the drug.
>
> But probably one of the most compelling one was that it was a very fast-acting agent. It worked very quickly to take effect, and it wore off very quickly when you stopped the drug.

(*Id.* at 859.)

Abbott first began to sell sevoflurane, a product it labeled as Ultane, in glass bottles beginning in 1995. (*Id.* at 860.) In January 1995, the food and drug administration (FDA) approved the new drug application Abbott had submitted for Ultane. (*Id.* at 819, Leticia Delgado.) Abbott did not, however, commercialize the product until June 1995. (*Id.*) Thus, the five-year market exclusivity that accompanied the FDA's approval of Abbott's new drug application did not expire until June 2000. (*Id.* at 1483, Dr. Lessor.)

Between June 1995 and January 26, 1996, Abbott sold 79,000 bottles of sevoflurane with water from 23 different lots. In late 1996, Abbott discovered that some bottles of sevoflurane from one lot had begun to degrade. (*Id.* at 1133.) The product in these bottles had developed a very pungent odor and murkiness. (*Id.*)

The degraded sevoflurane created a grave problem because it produced a harmful byproduct, hydrofluoric acid. (*Id.* at 25.) Hydrofluoric acid is very dangerous because if inhaled, it can cause death. (*Id.*) As a result, that particular lot was recalled. (*Id.* at 132, 1150.)

Abbott immediately investigated, and Dr. Keith Cromack, one of its scientists, concluded that the degradation of sevoflurane occurred because of a rusty valve, or valves, in the stainless steel shipping containers ("tycons") that were used to transport sevoflurane from Central Glass of Japan, which manufactures all of the sevoflurane for Abbott. (*Id.* at 69-85.) Reports explaining Dr. Cromack's findings regarding the origin of the degradation of Abbott's sevoflurane are found in PXs 411, 21 and 315. (*Id.* at 1139-46.)

Dr. Cromack concluded that the sevoflurane degradation was caused by exposure to Lewis acids. (*Id.* at 1145.) Lewis acid is simply defined as any chemical species that has a deficiency of electrons. "In a broad sense, Lewis acid is anything that is electron-deficient. It's looking for electrons to bind with, essentially." (*Id.* at 65, Dr. David Loffredo; PX 572.) Lewis acid inhibitors have the ability to donate electrons to bind with Lewis acids thereby neutralizing the Lewis acid. (Tr. at 44.) Sevoflurane contains two extra electrons on one of its oxygen atoms that seek to bind to Lewis acids. (*Id.* at 224-25.) When Lewis acid binds to sevoflurane, it causes the sevoflurane to break down, degrade, into a wide variety of products, some of which

are harmful to humans. (*Id.* at 87-88, 226.) Because there are so many different potential pathways for these binding interactions to occur during the degradation process, the process is considered a complex chemical reaction. (*Id.* at 82-83, 226; PX 518.)

Lewis acids can be found almost anywhere in the environment. The most common source of Lewis acids are metals. (*Id.* at 65.) When metals get oxidized the resulting metal oxides are Lewis acids. (*Id.*) Rust is a common example of a material that is Lewis acidic. (*Id.* at 223.) So any place containing metals that are exposed to the air and can be oxidized can contain Lewis acids. (*Id.*) Rust typically will not degrade sevoflurane because the rust molecules are neutralized by moisture from the air. (*See id.* at 299.) If, however, the rust is exposed to heat or acid, the water is driven off and the rust may become an activated Lewis acid. (*Id.* at 778.) Before Abbott's investigation in the Fall of 1996, it was unknown that Lewis acids would increase sevoflurane degradation. (*Id.* at 82-83, 231-32.)

In the fall of 1997, some ten or eleven months after the application for the '176 patent had been filed, Abbott again recalled its sevoflurane product. (*Id.* at 132, 892; DX 136.) During its second recall investigation, Abbott discovered that its glass container was involved in the chemical reaction that was causing the degradation. (Tr. at 133.) Hydrofluoric acid, it was found, has the ability to etch glass. (*Id.* at 232.) Acidic etching of glass can expose and activate further Lewis acid species (silicon fluorides) within the glass itself. (*Id.*; *see id.* at 498-99.) This can cause what is called a cascading reaction in which the Lewis acid released from the glass container itself causes further degradation of the sevoflurane which in turn produces more hydrofluoric acid which causes even more etching thereby releasing more Lewis acid. (*Id.* at 95-96.) The cascading reaction has not been seen in any other (non-glass) container. (*Id.* at 151.) In

fact, Abbott presently does not use a glass container. (*Id.* at 67.) It has developed and patented a container made of Polyethylene naphthoate, referred to as a "PEN," container which contains no Lewis acid in its makeup. (*Id.*)

During the recall investigation, Abbott scientists discovered that they could solve the degradation problem by neutralizing Lewis acids by exposing them to water. (*Id.* at 98, Dr. Loffredo.) Water interacts with Lewis acids by forming a chemical bond between the acids and the empty oxygen orbital on the water molecule. (*Id.* at 232-33, Dr. Jung.) This inhibits degradation by deactivating Lewis acids which would otherwise attack sevoflurane at its ether and halogen linkages and release hydrofluoric acid into the anesthetic. *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1275 (Fed. Cir. 2003). In the words of Abbott witness and patent inventor Dr. Loffredo: "You could put a certain amount of water in and cut off the degradation process, and this was – I think the significance of this was to show that if you had an inadvertent introduction of Lewis acids, this idea of sprinkling in, okay, that certainly the water present at an appropriate level would stop that from causing a reaction to proceed." (Tr. at 116, Dr. Loffredo.) Based upon this finding, Abbott filed for the '176 Patent on January 27, 1997, which issued on November 23, 1999. (*Id.* at 1041); *see Abbott*, 334 F.3d at 1275.

Prior to this discovery, Abbott had always sought to minimize the amount of water contained in its sevoflurane product.

> Q. Prior to your work in the fall of 1996 with Dr. Cromack and the others, did you have any understanding as to the role of water in the Abbott sevoflurane product?
>
> A. Yes, I did.
>
> Q. And what was that understanding?

> A. My understanding is that there was a desire to minimize the amount of water, to bring down the water level in sevoflurane.

(Tr. at 98, Dr. Loffredo.)

Five chemical compounds other than water were also found potentially to have the same useful effect and are listed in claim numbers 1 and 6 of the '176 patent. Water was chosen because it posed no possible risk of harm to humans and would not require any complicated regulatory approval. (*Id.* at 102.)

In April 1998, Ohmeda, Inc. sought to bring their new sevoflurane product, containing less than 130 parts per million ("ppm") of water, to market by filing an Abbreviated New Drug Application ("ANDA") with FDA. Baxter acquired Ohmeda, Inc. in April 1998. (*Id.* at 1487.) After placing the sevoflurane project on hold for a few months, Baxter decided to bring sevoflurane to market. (*Id.* at 1488.) An amended ANDA was filed with the FDA on January 26, 2001, which differed from the original application because it sought to manufacture sevoflurane in Baxter's aluminum epoxy phenolic resin-lined container. (*Id.* at 1534; DX 271, Revised ANDA.) In its application to the FDA, Baxter made a paragraph IV certification that its sevoflurane product does not infringe the '176 patent. *Abbott*, 334 F.3d at 1275. The filing of the initial ANDA by Baxter led Abbott to file an infringement action in this Court.

DISCUSSION

Claim Construction

At issue is whether Baxter's sevoflurane product, containing no more than 130 ppm of water, falls within the claims of Abbott's '176 Patent. Claim 1 of the Patent states:

> What is claimed is:
>
> 1. An anesthetic composition comprising:
>
> a quantity of sevoflurane; and
>
> a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol.

(PX 1, '176 Patent, Claim 1, Col. 11, Lines 21-28.)

In its review of this Court's construction of that claim, the Federal Circuit held that the phrase "in an effective amount" means "the amount of Lewis acid Inhibitor that will prevent the degradation of sevoflurane by a Lewis acid." *Abbott*, 334 F.3d at 1277-78. Thus, this Court is left with the task of construing the phrase "to prevent degradation" to determine whether the Baxter product has a sufficient amount of water to prevent degradation and, therefore, infringes Abbott's '176 patent.

When construing a claim, intrinsic evidence – the language of the patent and its prosecution history – is considered first. *Metabolife Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004) ("In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention.") The Court gives the words of the claim the ordinary and customary meaning that

they "would have to a person of ordinary skill in the art in question at the time of the invention," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), unless it appears from the specification or the file history that they were used differently by the inventor. *Carroll Touch, Inc. v. Electro. Mech. Sys. Inc.*, 15 F.3d 1573, 1577 (Fed. Cir. 1993).

Sometimes, "the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges." *Phillips*, 415 F.3d at 1314. In other cases, like this one, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art." *Id.* To divine the ordinary meaning of claim language in those cases, courts may use "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean," including "extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* (quotation omitted).

If the meaning of a disputed term is clear from the intrinsic evidence, as informed by evidence about the relevant technology, then no extrinsic evidence as to the proper claim construction may be used. *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 715 (Fed. Cir. 1998). If, however, intrinsic evidence does not fully illuminate the meaning of a claim, a trial court may rely on extrinsic evidence, including expert testimony. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

The phrase "to prevent degradation" is not defined in the Patent. Thus, we must determine what a person of ordinary skill in the art would have understood that term to mean at the time the application for the '176 Patent was filed.

It is clear that the word prevent, as used in the phrase "to prevent degradation" is a term of art. In laymen's terms, "to prevent" means "to keep from happening." *See* WEBSTER'S NEW WORLD DICTIONARY 1067 (3rd College ed. 1988). But Drs. Loffredo and Jung, both of whom are skilled in the art, agree that it is impossible to stop all degradation of sevoflurane. Dr. Loffredo testified:

> Q. When you did your analysis and concluded that Claim 1 of the Abbott water patent covered the Baxter product with 130 parts per million of water, did you assume that the use of the word "prevent" meant that all degradation must be prevented in order for the amount of water to be effective?
>
> A. In this context, the word "prevent," you can never prevent all degradation. There will always be some level of degradation in any product.

(Tr. at 435, Dr. Loffredo.) Similarly, Dr. Jung testified:

> [To] slow down, essentially, and inhibit, make it slower. You never get zero degradation. The likelihood of having something which is 99.999 percent pure is extremely low. There's always some degradation. And so what "prevent degradation" means is to slow it down so that the material is not very degraded. That is, it is inhibited the degradation process.... [I]t's very had to get any compound with no degradation. It's essentially impossible.

(*Id.* at 239.) If it is not possible to prevent all degradation, then the term "prevent degradation" as used in the patent must mean to prevent degradation past a certain point.

The next step then, must be to determine what that point is. In other words at what level is degradation so great that the amount of Lewis acid inhibitor has not been sufficient to "prevent degradation." Or to put it another way, when, according to the teachings of the patent to one of ordinary skill in the art is sevoflurane deemed to be degraded. Dr. Jung says the term is

illuminated by the experiments described in examples 1-6 in the Patent. Those experiments were performed by Abbott during its investigation to determine if sevoflurane degraded after being exposed to a Lewis acid.

Abbott used activated alumina in its tests. Activated alumina is made using a chemical called aluminum oxide. If you take aluminum oxide and heat it or treat it with hydrochloric acid, you can activate the Lewis acid by driving off the water molecules that are normally present. Thus activated, the alumina will cause the sevoflurane to degrade. Abbott chose alumina as the Lewis acid with which to conduct its tests because it was what Abbott's scientists thought would be present in many circumstances and was certainly present in the glass container itself.

The test described in example 1 of the Patent involved sprinkling alumina into a container of sevoflurane and then incubating it to accelerate the reaction which, without incubation, would take six to nine months to occur. After heating the mixture, Abbott looked for degradation. Next, Abbott added water to the mix and did the same experiment to see if the water was effective in preventing degradation. In this first example, Abbott took 20, 10 and 50 milligrams, respectively, of the Lewis acid and added it to sevoflurane, incubated the mixtures and then analyzed them. The results, according to Dr. Loffredo, demonstrated the Lewis acid-inhibiting quality of water:

> You could put a certain amount of water in and cut off the degradation process, and this was -- I think the significance of this was to show that if you had an inadvertent introduction of Lewis acids, this idea of sprinkling in, okay, that certainly the water present at an appropriate level would stop that from causing a reaction to proceed.

(*Id.* at 116, Dr. Loffredo.)

Another experiment, reflected in example 2 of the Patent, involved putting sevoflurane into a glass ampule that was flame-sealed to cause the formation of Lewis acid sites. Once formed, the Lewis acid sites caused the sevoflurane to degrade. Abbott did the same thing with another flame-sealed glass ampule, but the sevoflurane in this ampule was saturated with water. Abbott then heated both of the ampules at a high temperature. The results: the non-saturated sevoflurane degraded while the sevoflurane saturated with water did not. Dr. Loffredo referred to this as "sort of an on-and-off mechanism . . . . You've introduced an active Lewis acid site, and you've stopped that site from degrading sevoflurane by the addition of the inhibitor." (*Id.* at 118, Dr. Loffredo.)

Abbott expanded on its second experiment in the test described in example 3. Instead of using one ampule, it used multiple ampules with varying levels of water and varying levels of heat. The results showed that a water level of 595 ppm produced a pH of 5 and very low levels of degradation. With water levels of 303 ppm, 206 ppm, and 109 ppm, respectively, the results showed high levels of degradation.

Example 4 of the Patent describes additional ampule experiments at what Dr. Loffredo testified was a more reasonable temperature range, *i.e.*, 60 degrees for 144 hours and 40 degrees for 200 hours, as depicted in Table 3. Under these conditions, sevoflurane with 109 ppm of water had a pH of zero, indicating a high acid concentration, and large quantities of degradants. The degradation was minimized when more water was added. Example 4 suggests that as the temperature increases, the amount of water required to inhibit the degradation of sevoflurane will also increase.

The experiment described in example 5 is similar to the first experiment. It was designed to assess what happened in an actual bottle that Abbott used to package its sevoflurane. Abbott took glass containers that had been previously etched, so the surface was known to be Lewis acid activated, and added sevoflurane with water to them to demonstrate that a Lewis acid inhibitor would inhibit the degradation that had occurred in the glass bottles of sevoflurane that Abbott had previously recalled. The tests showed that sevoflurane in previously etched bottles would degrade, but the degradation was inhibited by adding 400 ppm of water.

In example 7, Abbott rolled a previously etched glass container in saturated sevoflurane and then tested it in the same way as in example 5. The idea was to coat the etched glass with water to see if the coating would prevent degradation. The result was that the sevoflurane experienced virtually no degradation. Dr. Jung says that this example demonstrates not only that coating a container with a Lewis acid inhibitor decreases degradation, but that the container itself can be a Lewis acid inhibitor. (Tr. at 247.)

According to Dr. Jung, a person of ordinary skill in the art would conclude from the patent examples that degradation as it is used in Claim 1 means sevoflurane with total impurities of 4000 ppm or more. (*Id.* at 287.) Conversely, a person of ordinary skill in the art would understand that sevoflurane with less than 4000 ppm of degradants is not degraded. (*Id.* at 241.)

Dr. Jung based this conclusion primarily on his reading of example 6 of the patent. When asked how the '176 patent defines degradation, Dr. Jung replied by referencing Table 6 (columns 9 and 10), which reflects the results of example 6. (*Id.* at 239-40.) Dr. Jung said that Table 6 shows that when only 20 ppm of water is added to sevoflurane that had been introduced to Lewis acid, large amounts of degradation – from 4100 to 6500 ppm of impurities – resulted. (*Id.*)

However, when 400 ppm of water was added to the sevoflurane, the number of degradants was reduced to a range of approximately 100 to 600 ppm. (*Id.*)

According to Dr. Jung, Figures 4 and 5 of the Patent, which are bar graphs of the impurity levels in the sevoflurane tested in examples 5 and 6, also demonstrate that degradation of sevoflurane is inhibited by the addition of water at 400 ppm. (*Id.* at 240.) Dr. Jung says the graphs in Figures 4 and 5 show no impurities in the sevoflurane with 400 ppm of water tested in example 6 and at least 4100 ppm of impurities in the sevoflurane with only 20 ppm of water. (*Id.*) From these graphs, Dr. Jung concludes that a person of ordinary skill in the art would interpret the word degraded as it is used in the '176 Patent to mean sevoflurane with no less than 4000 ppm of degradants. (*Id.* at 239-40, Dr. Jung.)

But the Patent does not say that the study group with 400 ppm of water is not degraded. Rather, it says that Figures 4 and 5 "demonstrate that the degradation of sevoflurane is inhibited by the addition of water at 400 ppm." (PX 1, Col. 10, Lines 38-40.) In fact, at column 10, line 25, the Patent states that the HFIP concentration, which indicates the presence of hydrofluoric acid, of that study group is "quite high and suggests that the glass surfaces were still somewhat active." This language directly contradicts Dr. Jung's contention that the study group is not degraded.

Moreover, even a cursory examination of the graphs in Figures 4 and 5 reveals that they cannot bear the weight that Dr. Jung ascribes to them. Based on the visual representations of the bar graphs in Figures 4 and 5, Dr. Jung equates "inhibited," as it is used to describe those Figures, with eliminated: "[I]f you look at those bar graphs and you see bar graphs going off scale for the control group and you see zero bar graph for the other, that tells me this is

undegraded." (Tr. at 290, Dr. Jung.) The visual representations, however, are clearly imprecise. They are extremely small – occupying no more than a few inches in the center of an 8 ½ x 11 inch page – and measure impurities by the thousands of parts per millions. It is impossible to tell from these tiny, summary graphs precisely what level of impurities was found in any bottle tested.

Moreover, the conclusion that Dr. Jung draws from these graphs contradicts other portions of testimony. At one point, Dr. Jung testified that a person skilled in the art would understand the word degradation to refer to the pH level of the sevoflurane. (*Id.* at 243.) In his view, sevoflurane with a pH level of 1.5 is highly degraded. (*Id.*) Dr. Loffredo, who performed the tests described in the Patent, said that bottle 1 in Example 6, had a pH level of 1.5. (*Id.* at 500.) Yet, according to Dr. Jung, Figures 4 and 5 of the Patent show that bottle 1 of example 6 was not degraded. (*Id.* at 240-41.)

Like his reading of Figures 4 and 5, Dr. Jung's pH theory does not hold up to scrutiny. According to Dr. Jung, Table 2, column 7, of the patent differentiates between a pH reading of 0, which is extremely acidic, and a pH readings of 5 and above, which are described in the language below the table as reflecting the inhibition of degradation of the sevoflurane. (*Id.* at 243.) In Dr. Jung's view, Table 2 demonstrates that a pH reading of 5 or higher is non-degraded. (*Id.*) Table 3, Dr. Jung said, narrows the pH range further, by teaching that a pH level of 3.5 is degraded while a level of 5.0 is not degraded. (*Id.* at 243-44.)

Dr. Jung admits that the Patent does not explicitly define as degraded sevoflurane with a pH level between 3.5 and 5.0. (*Id.* at 244-45.) But, he said, a person of ordinary skill in the art would know that sevoflurane with a pH level of 4 and above is not degraded because that is the

pH level of many foods people commonly consume. (*Id.*) Because vinegar, Coca-Cola and orange juice, for instance, have pH levels as low as 3.5 and they do not harm us, the use of sevoflurane with a pH level of 4.0 should not harm us either. (*Id.*)

Dr. Jung's conclusion rests on the assumption that lung and mucous tissue have the same ability to tolerate inhaled, acidic sevoflurane as the stomach has to tolerate acidic foods in solid or liquid form. This seems a highly dubious assumption and, at any rate, one for which there is no support in the record.[2]

Moreover, Dr. Loffredo, who is also skilled in the art, contradicted Dr. Jung's testimony. According to Dr. Loffredo, a trained scientist would conclude from the patent examples that there is no single pH cutoff point below which sevoflurane is considered degraded. (*Id.* at 484-87.) Rather, Dr. Loffredo said a person skilled in the art would understand that no conclusion about the pH level dividing line can be drawn from any single experiment, but must be drawn from the entire data set, that is, all of the examples in the patent. (*See id.* at 505, Dr. Loffredo ("[The pH] value is subjective and depends upon the nature of the experiment that you're doing.").)

Given the contradictory testimony of Drs. Jung and Loffredo, the Court concludes that intrinsic evidence is insufficient to determine the ordinary meaning of the term "degradation" to persons skilled in the art. Thus, The Court will turn to extrinsic evidence for guidance.

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[2] During cross examination regarding another matter, Dr. Jung volunteered that he is not an expert on patient safety. (Tr. at 281, 283, 294.) He seems to forget this self-proclaimed limitation on his expertise when he offers this opinion, which amounts to nothing less than an opinion as to how acidic sevoflurane can still be safe for patient use.

Sources of extrinsic evidence are the specifications for various sevoflurane products. According to Dr. Loffredo, those specifications provide a practical measure of degradation: the amount of chemical change that renders the product useless during its announced shelf life. (*See id.* at 375-76, 435-37, Dr. Loffredo.) After all, the purpose of producing sevoflurane is to provide a product that dispensers of medical services can use safely. If the Lewis acid inhibitor prevents the product from becoming so chemically decomposed or altered that it cannot be used during its shelf life, then it can be said to be sufficient to prevent degradation.

Dr. Cromack, one of the Patent's inventors, testified in a similar vein. In his view, if medical-grade sevoflurane becomes unusable because of exposure to Lewis acid, the sevoflurane would be considered degraded within the meaning of the Patent. (*Id.* at 1217-18, Dr. Cromack.) Moreover, he said, the sevoflurane is degraded if it falls outside the product specification. (*Id.* at 1308, Dr. Cromack.)

Baxter, Abbott, the FDA and the U.S. Pharmacopeia all have specifications that require sevoflurane to have less than 300 ppm of total impurities. (*Id.* at 437, 1506-07, 1576, Dr. Lessor; 376-77, Dr. Loffredo.) The Court, therefore, finds that for purposes of the Patent, sevoflurane is degraded if it contains degradants in amounts greater than 300 ppm.

Literal Infringement

Abbott, the patent owner, has alleged infringement and, therefore, has the burden of proving such by a preponderance of the evidence. *Centricut, LLC v. Esab Group, Inc.* 390 F.3d 1361, 1367 (Fed. Cir. 2004) (citing *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d

836, 842 (Fed. Cir. 1999)). Given the Court's construction of the disputed claim language, Abbott must establish by a preponderance of the evidence that Baxter's proposed product contains a sufficient amount of water to prevent Lewis acids from producing in the sevoflurane degradants in amounts greater than 300 ppm.

Abbott's experts Drs. Cromack and Loffredo performed a test to determine whether Baxter's product infringes the '176 patent. (Tr. at 1171.) In this test, Abbott put three samples of Baxter's sevoflurane in Abbott's PEN containers. In one of the containers, Abbott put approximately 25 ppm of water and 10 mg of activated neutral aluminum oxide, a Lewis acid. In the second container, Abbott put 25 ppm of water and 20 mg activated neutral aluminum oxide. In the third container, Abbott put 126 ppm of water and 10 mg of aluminum oxide. All three samples were then heated sufficiently to accelerate degradation. The first two samples degraded, the purity level fell below Baxter's specifications for the product, with the sample containing 20 mg of Lewis acids showing the most degradation. The third sample, however, did not degrade - the purity level of that product remained basically the same. Because the sample with 126 ppm of water did not degrade, Drs. Cromack and Loffredo concluded that the 130 ppm water level of Baxter's sevoflurane product, was effective to prevent degradation by Lewis acids. (*Id.* at 200 (Loffredo), 1200-01 (Cromack).)

Drs. Cromack and Loffredo said that they chose the amounts of Lewis acid used in their experiment because those are the amounts used in the Patent examples. (*Id.* at 140 (Loffredo), 1198 (Cromack).) Abbott believes that these amounts constitute a reasonable estimate of Lewis acid that a non-glass container would "see from the environment." (*Id.* at 145, Dr. Loffredo.) As to the 10 mg of activated alumina, Dr. Loffredo described this as being akin to the amount that

was scraped from the tycons' valves during the investigation into the degradation of Abbott's product. (*Id.*) He further indicated that although it was not a precise value (of alumina that a plastic container could expect to encounter from environmental sources), he believed it to be reasonable and an amount with which they had experience both from the patent experiments and from their experience in "handling manufacturing equipment and other potential sources of Lewis acid inhibition ."[3] (*Id.* at 145, Dr. Loffredo.)

Based upon these tests, Dr. Loffredo opined that Baxter's sevoflurane product infringes Abbott's Patent:

> Yes, I believe it does infringe our patent . . . . It has an effective amount of Lewis acid inhibitor to prevent degradation of Lewis acids . . . . The tests that we conducted lead me to that conclusion . . . . We used the high limit of 130 PPM as a model, and we subjected the sample to degradation by Lewis acid, and we found inhibition by this water level.

(*Id.* at 145-46, 1200-01.)

Baxter, however, complains that in testing its sevoflurane for infringement, Abbott designed an experiment that did not mirror any of the examples in the Patent. The closest Patent experiment to Abbott's test of Baxter's sevoflurane is example 1. That is the only Patent

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[3]Dr. Jung testified that he did not believe 625 milligrams of activated alumina (twelve and a half times as much as Dr. Loffredo used in Patent example 1) would be found in a bottle of Baxter sevoflurane. However, in a separate *Daubert* ruling this Court barred Dr. Jung's testimony as to how much Lewis acid is likely to be found in Baxter's sevoflurane because there was no scientific basis for such an opinion. The Court, therefore, gives no weight to such an opinion. Similarly, the Court gives no weight to the opinions of Dr. Loffredo and Dr. Cromack as to the amount of Lewis acid to which the environment exposes a non-glass container because they are, as far as the record reveals, not based upon anything more than their unsubstantiated beliefs.

experiment in which Lewis acid was added to the sevoflurane. But, as Baxter points out, the Abbott infringement experiment did not use the same proportions of activated alumina and sevoflurane as was used in example 1 of the Patent. In the infringement tests, Abbott used much less Lewis acid in proportion to the amount of sevoflurane than was used in example 1 of the patent, about one-tenth as much.[4] Using a lower concentration of Lewis acid makes it more likely that any given amount of water will be sufficient to prevent degradation, thereby tending to prove infringement. Or as Dr. Jung, one of Abbott's expert witnesses, put it on cross examination:

> If I wanted to test in 250 milliliters of the Sevo, Baxter Sevo, and have the same ratio, then I would have to use twelve and a half times as much alumina, because if I use less alumina I would get less degradation because you need more alumina to see more degradation.

(*Id.* at 273, Dr. Jung.)

> You're absolutely right. These are not done under the same set of conditions, so more alumina would have had to have been added to make them identical to the earlier Abbott studies.

(*Id.* at 278, Dr. Jung.)

> I believe if he had used much more, so twelve times as much, he would have seen more degradation. Would it have fallen out of the

[4]In example 1, the Abbott scientists added 10 mg, 20 mg and 50 mg doses of alumina to 20 mL of sevoflurane. In its infringement test of Baxter's sevoflurane, however, Abbott used the same amounts of alumina in 200 mL of sevoflurane. The Lewis acid was, therefore, greatly diluted. To maintain the same proportions in the infringement test as were used in example 1 of the Patent, Abbott would have had to use ten times the amount of alumina because it used ten times the amount of sevoflurane.

> specs for degradation? I don't know, but I think he would have seen more degradation.

(*Id.* at 279, Dr. Jung.)

Indeed, on cross-examination, both Drs. Loffredo and Jung admitted that they could not rule out the possibility that Baxter's sevoflurane would have degraded, if they had used proportionate amounts of activated alumina. (*Id.* at 523-24 (Loffredo), 277-78 (Jung).) Moreover, Dr. Cromack conceded that if Abbott had used 100 mg of alumina in its 200 mL of sevoflurane instead of the 10 mg it used, it was more likely that the sevoflurane would have degraded. (*Id.* at 1382, Dr. Cromack.)

Dr. Cromack, however, opines that what is important is not the proportion of Lewis acid to sevoflurane in the mixture, but the proportion of Lewis acid to water. (*Id.* at 1380, Dr. Cromack.) The Court is convinced, however, that Dr. Jung got it right when he stated that more degradation would likely have resulted from the use of a greater concentration of Lewis acid. Thus, we cannot know if Baxter's sevoflurane would have fallen out of the specification range for degradation, 300 ppm of impurities, had the experiment been conducted exactly as example 1 of the Patent had been conducted.

Baxter also criticizes the Abbott infringement experiment because of the amount of water used. In its infringement test, Abbott started with Baxter sevoflurane and attempted to add sufficient water to achieve a new level of 130 ppm of water. However, the technician doing the mixing originally missed the mark and raised the water content to 149.9 ppm. (*Id.* at 402, Dr. Loffredo.) To reduce the water content to approximately 130 ppm, the technician then mixed the sevoflurane with 149.9 ppm water content with some of the original sevoflurane. (*Id.* at 406, Dr.

Loffredo.) However, as Dr. Loffredo admitted on cross examination, the final moisture level of the Baxter sevoflurane that was used in the tests – after Abbott's attempts to adjust the water content – was never tested. (*Id.* at 405-08.) Therefore, the water content could have been as high as 146.4 ppm rather than 126 ppm, when the alumina was added to it.[5] If the water content of the Baxter sevoflurane that Abbott tested was actually as high as 146.4 ppm, Dr. Loffredo agrees that the results obtained would not necessarily be predictive of the results of a test of sevoflurane with only 130 ppm of water. (*Id.* at 411, Dr. Loffredo.)

Moreover, Baxter says, Abbott's attempt to adjust the sevoflurane's water content from 149.9 ppm to 130 ppm may explain why the sevoflurane degraded with only 22 ppm of water during the infringement test. Abbott's adjustment attempts exposed the sevoflurane to molecular sieve pellets which can, themselves, contain Lewis acid. (*Id.* at 1521, Dr. Lessor.) Thus, the very process of drying the sevoflurane may have exposed it to an entirely different source of Lewis acids.

Baxter further criticizes the infringement experiment because Abbott's scientists used a different and less acidic type of alumina in that experiment than they had used in Patent example 1. In example 1, Abbott used activated acidic alumina, while in conducting the experiment on

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[5]Even Dr. Loffredo was forced to admit that this was possible because an actual measurement was not done (Tr. at 410-11, Dr. Loffredo), and because of the possibility that water migrated from and through the PEN container while the test was being conducted. Based upon his fifty years of experience in the field, Dr. Charles Rogers opined that it would take months, if not years, for 20 ppm of water to migrate through the PEN bottle; although he agreed that he did not have a good basis for estimating the permeability of the PEN bottle and had not conducted the necessary experiments to measure permeability. (*Id.* at 796-97, Dr. Rogers.) Abbott has admitted that water will migrate into its PEN container at 25°C and 60% relative humidity. (*Id.* at 796- 800, Dr. Rogers).

Baxter's sevoflurane Abbott used activated neutral alumina. (*Id.* at 1383-84, Dr. Cromack.) Dr. Cromack says that there is no difference in degree of activity, as it pertains to the degradation of sevoflurane, between acidic and neutral activated alumina. (*Id.* at 384-85, Dr. Cromack.) Baxter's expert, Dr. Lessor, on the other hand, testified that when you treat alumina with hydrochloric acid and subject it to heat, thus creating acidic activated alumina, chlorine atoms become directly attached to the alumina. Because chlorine atoms have a very high affinity for electrons, this has a tendency to pull the electrons away from the alumina. (*Id.* at 1556.) That makes the alumina more positively charged, so that the empty orbital present in the alumina develops a greater affinity for the electrons on the Lewis base thus making the acidic alumina a stronger Lewis acid than it would otherwise have been. (*Id.* at 1555-56, Dr. Lessor.) If Dr. Lessor is correct, then the failure of Baxter's sevoflurane to degrade may not be due to the presence of a sufficient amount of water but to a lack of any chemical reaction from the weaker neutral activated alumina. Clearly, Abbott's infringement testing of Baxter's sevoflurane would be more convincing if Abbott's scientists had used the same type of activated alumina as they used in testing their own sevoflurane in example 1 of the Patent.

Yet another of Baxter's challenges to Abbott's infringement test lies in Abbott's choice of containers. Abbott tested Baxter's sevoflurane by placing it in Abbott's PEN container, rather than in Baxter's own epoxy phenolic resin-lined non-glass container or in a glass container like that used in the Patent examples. According to Dr. Loffredo, that choice was made to avoid confusion from any role Baxter's liner, which Abbott was unable to test, might play in the results. (*Id.* at 134.) In Dr. Loffredo's opinion, Abbott's PEN container was the only proven

inert, neutral environment that would not contribute in any way to the degradation of Baxter's sevoflurane. (*Id.* at 138.)

Baxter, however, correctly argues that in cases arising out of an ANDA, the infringement issue is defined by the specification in the ANDA itself. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). Because Baxter's ANDA specifies the use of the lined aluminum bottle, the question before the Court is whether Baxter's sevoflurane, packaged in the lined aluminum bottle, has an effective amount of Lewis acid inhibitor. An effective amount of Lewis acid inhibitor in one bottle may not be an effective amount in a different type of bottle. *See Abbott*, 334 F.3d at 1278 ("Moreover, the '176 specification teaches that an effective amount of any given Lewis acid inhibitor will vary depending upon the conditions to which sevoflurane is subjected.") Therefore, to test whether Baxter's product contains an effective amount of water it must be tested under the conditions to which it will be subjected. One of those conditions, is the container in which it is stored.[6]

Abbott's expert witnesses, Drs. Loffredo and Cromack, were both ambivalent about whether the test would have yielded the same results if Baxter's epoxy phenolic resin-lined

[6]Abbott argues that Baxter's sevoflurane will be exposed to Lewis acids from the metal particles from its aluminum container. Further, Dr. Jung testified that Lewis acids exist in Baxter's epoxy phenolic liner itself. Of course, Dr. Jung also testified that Baxter's liner was itself a Lewis acid inhibitor. (Pls.' Initial Post-Trial Submission at 11; Tr. 256-58; PXS 333, 334.) From these very arguments, it becomes clear that the conditions to which Baxter's sevoflurane will be exposed are not in any way approximated by testing it in Abbott's PEN container.

aluminum container had been used. Each testified at trial that he would expect the same results, but in their depositions each testified that he did not know if the results would be the same.

Overall, the infringement experiment raises more questions than it answers. In that experiment, Abbott used 10 mg of Lewis acid because 5 to 10 milligrams of rust had been scraped from one of the tycons of one of Abbott's recalled glass containers. (*Id.* at 145.) Because there were other valves with similar levels of corrosion, Dr. Loffredo surmised that similar amounts could be obtained from the other valves as well. (*Id.* at 169.) No precise measurements were done, however, and how this information translates into the amount of Lewis acid likely to be found in a 250 milliliter bottle of Baxter's sevoflurane is a mystery. Further, the amount of Lewis acid present in any of the tycons that was not visible to the naked eye as rust was never measured or estimated. (*Id.* at 170-71.) The amount of Lewis acid that may have migrated into Abbott's sevoflurane from the rust on any of the valves is also not known. (*Id.* at 173.)

The experiments described in the Patent are similarly flawed. When asked why Abbott chose the amounts of Lewis acid used in example 1, Dr. Loffredo responded:

> These amounts took into account what we thought were the potential sources of Lewis acids at the time and took into account that we had a reactive glass vessel that we were using and that it also might contribute Lewis acids. So the amounts were, I think, spread over a wide range because of that. We wanted to explore this in some detail. This was an exploratory tool for this process.

(*Id.* at 117, Loffredo.) While this response tell us that Dr. Loffredo considers 10 to 50 milligrams of Lewis acid to be a wide range, it does not tell us on what that opinion is based.

When asked how he accounted for the amount of Lewis acid coming from the glass container, Dr. Loffredo testified:

> Well, we don't have exact values of what we would estimate would be in the environment because it's somewhat difficult to estimate. We can certainly try to bracket it. And when you take into account the participation of the glass vessel, we thought, you know, the glass vessel has alumina in it. It's not completely made of alumina. We can also reasonably ascertain what level of alumina might be contributing to this process. And so that would give us a rough upper bound, in this case, of 50 ppm – I'm sorry, 50 milligrams.

(*Id.*, Loffredo.) We are given no real explanation, however, as to what Dr. Loffredo meant when he said "we can reasonably ascertain."

When asked how he would identify the amount of Lewis acids from all sources with which the sevoflurane might come into contact, Dr. Loffredo answered:

> It's very difficult to determine the exact amount of Lewis acids in the environment. You can, I think, provide a reasonable estimate based upon your experience with the product, your experience with the types of equipment used, either the filling equipment, the transport equipment and/or the anesthesia machines and the practice of use of the anesthetic. So I don't agree. I think that you can come up with an estimate.

(*Id.* at 131, Loffredo.) Nor do we know how much Lewis acid is believed to come from the production process, how much from the process of administering the sevoflurane to the patient, or how much, if any, from the environment in general. (*See id.* at 287 (Dr. Jung admitting that he has done no study to measure the amount of Lewis acid that could be produced in a vaporizer during its use in administering sevoflurane to a patient).)

It is clear from Dr. Loffredo's language that there is a great deal of uncertainty here. He admits that determining how much Lewis acid will be encountered is "very difficult." Further, all he seems to offer is a sort of vague hope: "You can, I think, provide a reasonable estimate . . . ." (*Id.* at 131, Loffredo.) He never gives us any hard facts upon which any reasonable estimates, much less any precise determinations, can be based.

As far as the record reveals, there is no hard data to support Abbott's belief that 10 to 50 milligrams of Lewis acid is a wide range or even a realistic estimate of the amount of Lewis acid to be found in either Abbott's or Baxter's sevoflurane. Without knowledge of how much Lewis acid needs to be neutralized, it is not possible to know if 130 ppm of water will be sufficient to do the job. And, therefore, no way to determine if this amount of water in Baxter's sevoflurane is effective to prevent degradation, regardless of how we define degradation.

Overall, there is very little evidence as to the amount of Lewis acid that the water must neutralize to be an effective Lewis acid inhibitor. The opinions of the experts with respect to the amount of Lewis acid that must be neutralized is no more than speculation, feelings based upon hunches without any studies, data, or even a thorough explanation of how the prior experiences of these scientists give them a basis for forming a credible opinion on this point. The unexplained inconsistencies between the Patent experiment and the infringement experiment and the admission of Abbott's experts that the infringement test results might have been different if proportionate amounts of Lewis acid and sevoflurane had been used, serves to point out both: (1) the importance of establishing how much Lewis acid must be neutralized to establish if sufficient water exists to prevent degradation; and (2) Abbott's inability to do so.

Abbott, of course, has the burden of proof as to infringement, yet its test of the accused product is so flawed in both design and execution as to make it unconvincing. For all of the reasons mentioned above, the Court finds that Abbott has failed to prove literal infringement.

Prosecution History Estoppel

Abbott also asserts infringement under the doctrine of equivalents. The doctrine of equivalents prevents competitors from easily duplicating inventions by making insubstantial changes to them in order to get around the existing patent. *Warner-Jenkins Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35-36 (1977). Baxter contends that the doctrine of prosecution history estoppel bars the application of the doctrine of equivalents in this case. The Federal Circuit has described prosecution history estoppel as follows: "[W]here the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question." *Festo Corp. v. Shoketsu, Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002). However, the patentee does not necessarily surrender his claim to all equivalents by submitting a narrowing amendment. Although the patentee by submitting a narrowing amendment "is deemed to concede that the patent does not extend as far as the original claim," this does not mean that the amendment thereby "relinquish[es] equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered." *Id.* at 736.

In the case at bar, Claims 1 and 6 of the '176 Patent originally claimed "a fluroether compound" but were amended to claim "sevoflurane," and originally claimed "a Lewis acid

inhibitor" but were amended to list six specific Lewis acid inhibitors. Thus, the amendment did, in fact, narrow the scope of the claims from a more general statement including any Lewis acid inhibitors to listing specific kinds. *Abbott*, 344 F.3d at 1281.

In *Festo Corp. v. Shoketsu, Kinzoku Kogyo Kabushiki Co.*, 535 U.S. at 733, the Supreme Court held that "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." Upon remand, the Federal Circuit held that "[i]f the patentee successfully establishes that the amendment was not for a reason of patentability, then prosecution history estoppel does not apply." *Festo Corp. v. Shoketsu, Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003).

Abbott argues that its narrowing amendment was not approved for reasons related to patentability. (Pls.' Initial Post-Trial Submission at 18.) Specifically, Abbott points out that it clarified with the examiner, before the amendment was issued, that the amendment was "not necessary in order to overcome the prior art cited during prosecution of the application." The prosecution history shows that the patent examiner agreed with Abbott and withdrew his §§ 102 and 103 rejections. (PX 3 at ABT 006710, 6723.)

Abbott further argues that the amendment to add the Markush group[7] of specific Lewis acid inhibitors was not made to satisfy the substantive requirements of § 112. It argues that the examiner never rejected the claims under § 112, but rather only rejected the claims under §§ 102 and 103. (*Id.* at ABT 006671-72, ABT 006708.) It avers that estoppel, therefore, does not apply

[7]"A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C." *Abbott*, 334 F.3d at 1280.

because *Festo* "speaks in terms of amendments made in response to rejections." (Pls.' Initial Post-Trial Submission at 17.) Abbott maintains that the record does not establish that the examiner ever threatened a § 112 rejection, and that, when read correctly, the statement by the patent examiner can only mean that he did not believe that adding specific Lewis acid inhibitors to the claim was necessary to comply with the substantive requirements of § 112. Thus, Abbott's amendment was not made for reasons relating to patentability.

The Federal Circuit, however, found that the purpose of the amendment adding the Markush group was "to comply with 35 U.S.C. § 112 and gain allowance." *Abbott*, 334 F.3d at 1281. That finding is the law of the case and, under *Festo*, such a narrowing amendment creates a presumption that the entire territory between the original claim limitation and the amended claim limitation has been surrendered. Unless the presumption is overcome, any doctrine of equivalents claim is barred by prosecution history estoppel.

To rebut the presumption of prosecution history estoppel, plaintiffs need to establish that: (1) the alleged equivalent would have been unforeseeable at the time the narrowing amendment was made; (2) the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent at issue; or (3) there was some other reason suggesting that the patentee could not reasonably have been expected to describe the alleged equivalent. *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1140 (Fed. Cir. 2004). The Court agrees with Baxter that no such showing has been made.

The record fails to establish unforeseeability. In determining foreseeability, the Court must determine whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment. *Festo*, 344 F.3d at 1369. Plaintiffs' own expert

witnesses testified that the use of epoxy liners to inhibit Lewis acid degradation would have been foreseeable in 1998. (Tr. 426-27, Dr. Loffredo; 632, 762-63, 776, Dr. Rogers; 351, Dr. Jung.) Dr. Rogers also testified that it has been known for about twenty years that an epoxy phenolic resin is a suitable lining for containers of pharmaceutical products in which purity is important. (*Id.* at 776, Dr. Rogers.) Thus, the use of an epoxy phenolic resin liner with Abbott's sevoflurane product was foreseeable. Further, Dr. Jung testified that it was foreseeable that two different Lewis acid inhibitors could be used in the same container to inhibit degradation. (*Id.* at 346-47, Dr. Jung.) "The Supreme Court in *Festo* neither excuses an applicant from failing to claim 'readily known equivalents' at the time of application nor allows a patentee to rebut the *Festo* presumption by invoking its own failure to include a known equivalent in its original disclosure." *SmithKline Beecham Corp. v. Excel Pharm., Inc.*, 356 F.3d 1357, 1364 (Fed. Cir. 2004). Furthermore, if Abbott's patent is read to include anything within a phenolic group, it would encompass "thousands" of other Lewis acid inhibitors not listed. If such was Abbott's intent, it ought to have retained its general "Lewis acid inhibitor" language, instead of describing in its claims a specific list of only six such substances.

Plaintiffs can also avoid the application of prosecution history estoppel by demonstrating that "the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question." *Festo*, 344 F.3d at 1368-69.

> [T]he inquiry into whether a patentee can rebut the *Festo* presumption under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment. . . . [T]hat reason should be discernible from the prosecution history record, if the public notice function of a patent and its prosecution history is to have significance.

Id. at 1369 (referencing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 309-40 (1997)).

No such reason is discernible from the prosecution history in the case at bar. On the contrary, Abbott's narrowing amendment limited the scope of the claim to the six specific Lewis acid inhibitors in the Markush group. "Thus, the plain meaning of asserted claims 1 and 6 limits them to a single Lewis acid inhibitor selected from the recited Markush group . . . ." *Abbott,* 334 F.3d at 1281.

The only other way for Abbott to avoid prosecution history estoppel would be to establish that there was "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Festo*, 535 U.S. at 740-41. The Federal Circuit has determined that such other reasons are few in number and cannot be relied upon "if the alleged equivalent is in the prior art." *Festo*, 344 F.3d at 1370. The only reason given by any witness for not including the epoxy phenolic resins in the claims description is that there would not be sufficient space to list them all. (Tr. at 428, Loffredo.) In addition, epoxy phenolic resins were part of the prior art. (*Id.* at 762-63, 776, Rogers.)

For the reasons given above, the application of the doctrine of equivalents is barred by prosecution history estoppel.

Infringement Under the Doctrine of Equivalents

Even if prosecution history estoppel were no bar, plaintiffs still could not prevail on a doctrine of equivalents theory. Through the doctrine of equivalents, the patentee can claim

insubstantial or trivial changes that are not encompassed in the drafting of the original patent claim. *Festo*, 535 U.S. at 733; *Honeywell*, 370 F.3d at 1139. The purpose of the doctrine of equivalents is to prevent competitors from easily duplicating inventions by making "insubstantial" changes to them. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35-36 (1997). Because the language in the patent may be an imperfect medium for communicating all possible nuances of the invention, the doctrine of equivalents helps ensure that "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo*, 535 U.S. at 731-32.

The "essential inquiry" in applying the doctrine of equivalents is whether or not "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention." *Warner-Jenkinson Co.*, 520 U.S. at 40. If the accused product "performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same overall result as the claimed invention," then the accused product can be said to infringe under the doctrine of equivalents. *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed. Cir. 1990) (quotation omitted).

The '176 Patent claims a method of preventing degradation of liquid sevoflurane from Lewis acids by adding a Lewis acid inhibitor, such as water, to the sevoflurane. Baxter packages sevoflurane in aluminum containers that are lined with an epoxy phenolic resin. Abbott alleges that Baxter's epoxy phenolic liner is "equivalent" to the six Lewis acid inhibitors listed in the claims of the '176 Patent. If we apply the "function-way-result" test to the facts of this case, the question becomes whether Baxter's epoxy phenolic liner is an "equivalent" Lewis acid inhibitor to the ones listed in the claims of the '176 Patent. The inquiry is an objective one, and subjective

intent must play no role in the application of the doctrine of equivalents test. *Warner-Jenkinson Co.*, 520 U.S. at 36.

The claims of the Patent require that the Lewis acid inhibitor, either water or a single Lewis acid inhibitor selected from the recited Markush group, be present in an amount effective to prevent degradation by Lewis acids. *Abbott*, 334 F.3d at 1281. Although Baxter's epoxy phenolic liner does not contain any of the inhibitors listed in the Patent, (Tr. at 125-26, Dr. Loffredo; PX 1, Col. 4, Lines 25–30, Col. 11, Lines 24-29), Abbott nevertheless argues that Baxter's liner, either alone or in combination with the water in the sevoflurane, is the equivalent of the claimed Lewis acid inhibitors, thus giving rise to infringement under the doctrine of equivalents.

Dr. Jung explained that Baxter's epoxy phenolic resin liner is a good Lewis acid inhibitor because it has many spots to inhibit Lewis acids. (Tr. at 296.) The ether molecules in Baxter's lining, he said, are well known to one skilled in the art to inhibit Lewis acids by the same mechanism, in the same manner, that water inhibits Lewis acid. (*Id.* at 350.)

But Dr. Jung also said that when Baxter's liner is combined with water, another good Lewis acid inhibitor, it is impossible to tell which is inhibiting degradation: the liner, the water or both. (*Id.* at 296-97.) Moreover, no one knows how many milligrams of activated alumina could be neutralized by the Baxter lining, because, to Dr. Jung's knowledge, it has never been tested. (*Id.* at 297.) According to Dr. Jung it is possible, although not probable, that the lining could have no inhibitory effect whatsoever. (*Id.* at 298.) Dr. Jung also admitted that since the Baxter liner remains in the bottle, unlike water, it will not be present to prevent Lewis acid

degradation once the sevoflurane enters a vaporizer. (*Id.* at 343.) In this way, Baxter's epoxy phenolic liner functions differently from the inhibitors claimed in the Patent.

Dr. Charles Rogers, Abbott's expert in the field of polymer science, testified that an epoxy phenol resin has the ability to stabilize effectively Lewis acids in sevoflurane. (*Id.* at 715.) Dr. Rogers further testified that the epoxy phenol resin would obtain substantially the same result in inhibiting Lewis acids in sevoflurane as would the Lewis acid inhibitors referenced in the Patent. (*Id.* at 723.) The epoxy phenolic resin has electron groups (the hydroxy groups) available to form covalent bonds with the Lewis acids in the same way that the low-molecular weight substituted phenolics referenced in the Patent do. (*Id.*) According to Dr. Rogers, it is the same component, the phenolic hydroxy group, in both the epoxy phenolic liner and the chemicals listed in Claim 1 of the Patent, that act to inhibit Lewis acids. (*Id.* at 717.) In Dr. Rogers' opinion, the epoxy phenolic material would inhibit the Lewis acids by the same organic chemical mechanism as the items listed in Claim 1 of the Patent. (*Id.* at 712-24.) Dr. Rogers believes that this chemical reaction is well-established and beyond question. He considers his opinion more certain than a mere theory that must be proven because the chemical mechanism upon which it is founded has been so well-established in science for so long. (*Id.* at 748-49.)

Having said that, however, he admitted that he had no tests to prove his opinion that the epoxy liner in the Baxter product actually inhibits Lewis acids. (*Id.* at 748, Dr. Rogers.) Dr. Rogers performed three tests, based upon well known chemical reactions and properties, in an attempt to bolster his opinion that Baxter's epoxy phenolic liner actually is a Lewis acid inhibitor. (*Id.* at 743, Dr. Rogers.) Two of the tests were inconclusive, in that they failed to

identify the composition of Baxter's liner. (*Id.* at 744-45.) The third test was stopped at the request of Abbott's counsel before any data was obtained. (*Id.* at 746-47.)

Dr. Rogers also admitted on cross-examination that Baxter's epoxy phenolic liner operates differently in some respects from the Lewis acid inhibitors claimed in the Patent. Because it is a solid and exists only along the walls of the container, its inhibitory action is limited to those Lewis acids that come into contact with the sides of the container. (*Id.* at 767.) The liner does not disperse itself in the sevoflurane solution as does water or any of the other substances claimed in the Patent. (*Id.*) Thus, it inhibits Lewis acid degradation in a different manner than the Lewis acid inhibitors in Claim 1 of the Patent. (*Id.* at 768, Dr. Rogers.) Further, because of this lack of ability to mix with the sevoflurane, and the fact that the liner's effectiveness has never actually been tested, there is reason to doubt that the Baxter liner will obtain substantially the same result as the method claimed in the Abbott Patent.

Abbott argues that Baxter presented no evidence at trial to rebut the testimony of Dr. Rogers. Baxter however, points to the testimony of Dr. Ralph Lessor, and argues that the studies performed by Baxter for submission to the FDA involved adding activated acidic alumina to Baxter's sevoflurane in Baxter's lined aluminum container. In each such case, the sevoflurane degraded despite the presence of the liner. Therefore, Baxter concludes that Baxter's tests have proven Dr. Rogers' opinion to be wrong.

Abbott also argues that the Baxter liner inhibits Lewis acid degradation by shielding the aluminum container from the sevoflurane. However, when preventing degradation in this manner, the Baxter liner is not performing the same function in the same manner as any of the claimed Lewis acid inhibitors. In performing this function, the Baxter liner is not involved in any

chemical interaction with the Lewis acids; there is no "covalent bond" formed between the Lewis acid molecules and the epoxy phenolic liner molecules. Rather, the Baxter liner is mechanically blocking the sevoflurane from coming into contact with the aluminum bottle which may contain Lewis acids.

Further, Baxter denies Dr. Rogers' claim that there are active Lewis acid sites in the aluminum of the Baxter bottle that will degrade sevoflurane. Baxter points to its own experiment in which it placed sevoflurane with 20 ppm of water into aluminum bottles without any liner. After heating them for as much as 43 days, none of the sevoflurane degraded beyond a total impurity level of 300 ppm. (*Id.* at 1506-08, Dr. Lessor.) From this test, Dr. Lessor concludes that "there were no active Lewis acid sites in the aluminum bottle that could cause degradation of sevoflurane." (*Id.* at 1508.)

As pointed out above, the patent owner has the burden of proving infringement. *Wilson Sporting Goods Co.*, 904 F.2d at 685. Abbott has presented insufficient evidence to establish infringement under the doctrine of equivalents. First, the record contains only the opinions of Dr. Jung and Dr. Rogers, based upon their understanding of generally accepted principles involving chemical reactions between certain types of molecules, as a basis for finding that Baxter's epoxy phenolic lining actually inhibits Lewis acid degradation. Neither Dr. Jung nor Dr. Rogers has performed any studies or tests that verify their opinions. The history of science is full of seemingly sound theories and conclusions based upon known scientific principles which, when tested, turned out to be incorrect. That is why testing is so fundamental to the scientific method.

Second, Dr. Lessor described actual tests performed with the epoxy phenolic liner that resulted in Lewis acid degradation of the sevoflurane. Those tests tended to show that the epoxy phenolic liner is, in practice, not an effective inhibitor.

In sum, the manner in which the epoxy phenolic liner might inhibit degradation is different in several respects from the manner in which the claimed inhibitors function. To the extent that the liner simply blocks sevoflurane from coming into contact with possible Lewis acid sites, it is not utilizing the chemical reaction that takes place when the claimed inhibitors are used. Further, the liner is not introduced into the sevoflurane to form a solution that contains the Lewis acid inhibitor within it, unlike all of the claimed Lewis acid inhibitors. Finally, because it does not form a mixture with the sevoflurane, the liner does not travel with the sevoflurane when it leaves the container, for example, when it is transferred to a vaporizer for delivery to the patient. Thus, it is not available to prevent degradation in that situation. For all of these reasons, the Court finds that liner does not obtain substantially the same result in substantially the same manner as the claimed inhibitors.

Invalidity - Anticipation

Baxter argues that the '176 patent claims are invalid because they are anticipated by the prior art. However, Baxter has the burden of proving invalidity by clear and convincing evidence. *Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371, 1386 (Fed. Cir. 2004).

> Patent law . . . establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed

> subject matter anticipates and invalidates. *See, e.g., EMI Group N. Am., Inc., v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.").

Schering Corp. v. Geneva Pharm., 339 F.3d 1373, 1379 (Fed. Cir. 2003). A prior art reference can anticipate and invalidate a claim even if the claim limitations are not expressly found in it, if the claim limitations are nonetheless inherent in it. *In Re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-50 (Fed. Cir. 2002). "[I]f a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim of an application, the claim is anticipated." *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986).

In November of 1995, approximately one year before Abbott discovered the method claimed in the '176 Patent, the application for the '211 patent was filed. (PX 414, '211 patent.) Thus, the '211 patent is prior art to the '176 Patent under 35 U.S.C. § 102(e). Baxter contends that the asserted claims of the '176 patent are anticipated by the "main distillate" in Illustration 1 of Table 2 of the '211 patent. This single prior art reference, Baxter argues, anticipates all of the asserted claims.

The '211 patent claims a method for removing a sevoflurane impurity called Compound A. (Tr. 307-08, Dr. Jung). In Illustration 1 of Table 2 of the '211 patent, a solution of 2% disodium phosphate and 98% water was mixed with 92.129% pure sevoflurane. (PX 414.) The mixture was then distilled. (Tr. at 308.) The sevoflurane produced in this manner is described in the '211 patent as "high purity" sevoflurane that "is used as a pharmaceutical and particularly as

an inhalation anesthetic." (*Id.* at 303.) The resulting, "main distillate," sevoflurane had total impurities of 50 ppm and was saturated with water. (*Id.* at 313.) Professor Girard testified that if one follows the directions given for Illustration 1 of Table 2, the "main distillate" sevoflurane produced will inherently be saturated with water and that this will occur in each and every case. (*Id.* at 1784, Prof. Girard.) The main distillate in Illustration 1 is sevoflurane saturated with water, which, as established in Example 2 of the '176 Patent, is an effective amount of Lewis acid inhibitor to prevent degradation. (*Id.* at 1170-71.) Thus, the main distillate constitutes a prior art reference that contains each and every claim limitation in claims 1, 2, 7, 9, and 10 of the '176 Patent.

Abbott's argument against anticipation centers around the principle that: "In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing' from the explicit disclosure of the prior art." *Schering Corp.*, 339 F.3d at 1379. Applying this principle, Abbott argues, shows that the '211 patent does not inherently disclose the invention of the '176 patent. In support of its argument, it points to testimony from Drs. Loffredo and Cromack that prior to their invention no one had any idea that Lewis acids had the potential to degrade sevoflurane. Further, no one was aware of the stabilizing effect water would have to prevent Lewis acid degradation. In fact, water was considered an impurity and was removed from sevoflurane to the extent possible during the manufacturing process that included the teachings of the '211 patent.

The '211 patent, Abbott says, teaches an intermediate step in the multi-step manufacturing process for sevoflurane. The result is not the final bulk sevoflurane product, let alone the final bottled sevoflurane product. The description of the process of the '211 patent

does not result in a disclosure of the final sevoflurane product with an effective amount of water to prevent Lewis acid degradation. A further step to dry the output of the process was determined necessary to remove further impurities. For these reasons, Abbott concludes: "A finished sevoflurane product with an effective amount of water, bulk or bottled, is not 'the natural result flowing from' the explicit disclosure of the '211 patent." (Pls.' Initial Post-Trial Submission at 24.)

In response, Baxter points out that what is important in evaluating anticipation is the physical properties of the prior art composition, not whether artisans in the field recognized those properties at the time. This principle is illustrated by *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342 (Fed. Cir. 1999). The patent-in-suit in that case covered a blasting composition with sufficient aeration to help initiate the explosion and an unsensitized water-in-oil emulsion. *Id.* at 1344-45. Two prior art patents disclosed blasting compositions that were within the claims of the patent-in-suit, but those patents said nothing about the importance of "aeration" in the blasting composition. *Id.* at 1346. The Federal Circuit concluded that both prior art patents contained examples with the required aeration although neither patent recognized the usefulness of trapped air in initiating the explosion. *Id.* at 1348. In fact, one of the patents taught that trapped air should be avoided. *Id.* at 1349. In holding that it was immaterial whether the "aeration" property of the prior compositions have been recognized or not, the court said: "Insufficient prior understanding of the inherent properties of unknown composition does not to defeat a finding of anticipation." *Id.* at 1348-49.

That holding is directly applicable to the case at bar. It matters not that the inherent Lewis acid neutralizing properties of the water-saturated sevoflurane produced in Illustration 1 of

Table 2 of the '211 patent were not appreciated at the time, or that a subsequent step in the manufacturing process was required to reduce the amount of water in the mixture. Once it is recognized that water at a level sufficient to prevent effectively Lewis acid degradation is an inherent element of the prior art composition – the sevoflurane mixture determined by Illustration 1 of Table 2 of the '211 patent – the assertion that water is an effective Lewis acid inhibitor amounts to no more than a claim to the discovery of an inherent property of the prior art, not the addition of a novel element. Insufficient prior understanding of the inherent properties of the known composition – the sevoflurane mixture determined by Illustration 1 of Table 2 of the '211 patent – does not defeat a finding of anticipation. All that is necessary is:

> [T]hat "the disclosure [of the prior art] is sufficient to show that the natural result flowing from the operation as taught [in the prior art] would result in" the claimed product. *In re Oelrich,* 666 F.2d 578, 581 (CCPA 1981); *accord MEHL/Biophile Int'l Corp.*, 192 F.3d at 1366; *see also Atlas Powder,* 190 F.3d at 1349–50 (affirming the district court's finding of inherent anticipation despite a finding that the inherent element could be avoided by taking "extraordinary measures" when practicing the prior art).

SmithKline Beecham Corp. v. Apotex, 403 F.3d 1331, 1343-44 (Fed. Cir. 2005).

A similar result was reached in *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373 (Fed. Cir. 2003). In that case, the district court found that the '233 patent (the prior patent) did not expressly disclose the substance DCL. *See id.* at 1378. Nonetheless, the district court found, and the Federal Circuit affirmed, that DCL was necessarily formed as a metabolite by carrying out the process disclosed in the '233 patent. *Id.* at 1378-80. The Federal Circuit concluded that the '233 patent anticipated claims 1 and 3 of the subsequent '716 patent, which expressly claimed DCL, under 35 U.S.C. § 102(b), and affirmed the district court's grant of

summary judgment as to invalidity. *Id.* at 1382. In so doing, the court rejected the contention that inherent anticipation requires recognition in the prior art. *Id.* at 1377.

The case at bar similarly involves the production of the claimed product, a mixture of sevoflurane and water in quantities sufficient to prevent degradation by Lewis acids, necessarily formed by carrying out the process disclosed in the prior patent. Yet, Abbott's point regarding the need for a natural result flowing from the disclosure of the prior art is well taken:

> Finally, we address Bristol's argument that new uses of old processes are patentable, that we should treat the expressions of efficacy as limitations because they distinguish the new use of the process over the prior art, and that claims should be read to preserve their validity. Bristol is correct that new uses of known processes may be patentable. However, the claimed process here is not directed to a new use; it is the same use, and it consists of the same steps as described by Kris. Newly discovered results of known processes *directed to the same purpose* are not patentable because such results are inherent.

Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001) (citations omitted) (emphasis added).

The comparison in this case is made more difficult by the fact that Claims 1, 2 and 9 of the '176 Patent assert a composition, not a process, while Claims 6, 7 and 10 describe a process. The purposes of the two patents, if not the same, are, at least very similar. Both describe steps necessary to produce a marketable sevoflurane anesthetic. Both describe steps to eliminate impurities. The difference, however, is that the '211 patent describes an intermediate step in production that eliminates compound A. It results in a mixture of sevoflurane and water that is not intended to be sold for use without further refinement; the patent's purpose was not to produce sevoflurane in its final useable form. The '176 Patent, on the other hand, involves a final step in production to prevent Lewis acid impurities from causing degradation. The two

processes are not directed to the same purpose, nor can it be said that the finished sevoflurane product with an effective amount of water, is a natural result flowing from the disclosure of the '211 patent. Thus, the asserted claims of the'176 Patent are not invalid on the grounds of anticipation.

Invalidity - Prior Sale

Baxter also argues that if the Court chooses to employ an after-the-fact test to evaluate what is an "effective amount" of water, then the asserted claims are invalid because of a prior sale. In August 1995, Abbott sold bottles of sevoflurane, which had at least 131 ppm of water and did not degrade, from its Lot 3298DK. Thus, one could conclude after the fact, without testing or analyses, that this sevoflurane must have had water in a sufficient amount to prevent degradation. John Wolfinger, Abbott's Divisional Vice President of Quality Center of Excellence for Drugs, confirmed that Abbott determined at the time of bottling that the water content of the sevoflurane from Lot 3298DK was 131 ppm. (Tr. at 576, Wolfinger; DX 51). In late 1996, sevoflurane from this lot was tested and found to be free of degradation. (Tr. at 583, Wolfinger.) The testing was done approximately one and one-half years into the product's two-year shelf life. 35 U.S.C. § 102(b) states that a person will not be entitled to a patent if "the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." If the sevoflurane in Lot 3298DK comes within the specifications of the '176 Patent, then its sale more than one year prior to the date of the application will invalidate the patent.

Baxter argues that the sevoflurane in Lot 3298DK contains an effective amount of water and, therefore, falls within the claims of the patent, because: (1) a representative bottle was tested one and one-half years after it was bottled and the sevoflurane had not degraded; (2) no customer ever complained about any bottle from that particular lot degrading; and (3) Abbott represented to its customers that the sevoflurane in that lot was safe. Abbott counters by pointing out that bottles from other lots, which had even more water, did degrade. (Tr. at 557-59, Wolfinger.) Therefore, Abbott says, the sevoflurane in Lot 3298DK could not have contained in effective amount of Lewis acid inhibitor. Abbott also argues that it is possible the sevoflurane in Lot 3298DK did not degrade not because it had sufficient Lewis acid inhibitor, but simply because it did not come into contact with any Lewis acids.[8]

This Court agrees with Abbott. It is not possible to tell, given all of the circumstances, whether the sevoflurane contained in Lot 3298DK failed to degrade because it had an effective amount of Lewis acid inhibitor, because it did not come into contact with any Lewis acid, or because it came into contact with a Lewis acid under conditions which, even absent the presence of a Lewis acid inhibitor, would not cause degradation to occur. Thus, the '176 Patent is not invalid for having been on sale in this country more than one year before the application was filed.

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[8]This, of course, is the same argument used by Baxter in explaining why its sevoflurane product will not degrade from Lewis acids even though it lacks an effective amount of Lewis acid inhibitor, an argument that Abbott disparages. (Pls.' Initial Post-Trial Submission at 11.)

Invalidity – Inequitable Conduct

Baxter also contends the '176 Patent is unenforceable because Brian Woodworth, the attorney who prosecuted the Patent application, committed inequitable conduct in doing so. Specifically, Baxter alleges that Woodworth failed to disclose material information with an intent to mislead the PTO, a violation of the duty to prosecute patent applications with candor, good faith, and honesty. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed. Cir. 2003); *Mollen's PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). "[I]f an applicant withholds material information from the PTO with intent to affect the allowance of claims, the applicant may be found guilty of inequitable conduct and the patent obtained would be rendered unenforceable." *Labounty Mfg., Inc. v. U.S. Int'l. Trade Comm'n*, 958 F.2d 1066, 1070 (Fed. Cir. 1992). The party alleging inequitable conduct must make a threshold showing of "materiality and intent to mislead or deceive the patent examiner." *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1261 (7th Cir. 2001). "[T]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

Baxter argues Woodworth failed to inform the patent examiner that: (1) Lot 3298DK was sold to third-party hospitals, stating instead that it was "distributed" by Abbott Laboratories (DX 15 at 6691); (2) the sales had taken place more than one year before the patent application was filed, stating merely that the lot was "distributed" before the "filing date" of the patent application (*id.*); and (3) a representative bottle from the lot had not degraded one and one-half years after bottling. Baxter argues that the information withheld was highly material because a

reasonable examiner would have been substantially likely to consider it important in deciding whether to allow the '176 Patent to issue. *Bristol-Myers*, 326 F.3d at 1234.

Indeed, it is a mystery why an attorney, trained in patent law and obviously aware of the significance of a prior sale as opposed to a prior free distribution, would describe the transaction using a word that could mean either, and which, therefore, would be of minimal help to the patent examiner. Woodworth not only failed to inform the examiner of the actual sale, he failed to inform him that the sale was prior to the bar date and that there was evidence that the sevoflurane so sold, which contained water, did not degrade.

Woodworth's explanation at trial, that he did not know whether Lot 3298DK had been distributed or sold is unconvincing. (Tr. at 1944, Woodworth.) All he had to do was ask. Indeed, he did ask, but his question was never answered and no explanation was given as to why. (*Id.* at 1972-73, Woodworth.) Apparently, the idea of being able to say, "I asked, and it's not my fault if nobody told me," was enough to satisfy Mr. Woodworth that he had complied with his duty of candor, good faith, and honesty. Even in criminal cases, where proof of guilt is required to be beyond a reasonable doubt, there is a jury instruction known commonly as the "ostrich" instruction. The "ostrich" instruction allows a jury to infer guilty knowledge beyond a reasonable doubt when the evidence shows that the defendant had a strong suspicion that someone had withheld important facts, yet shut his eyes for fear of what he would learn. Under such circumstances the jury is allowed to conclude that such a defendant acted knowingly. *See, e.g., United States v. Hauert*, 40 F.3d 197, 203 (7th Cir. 1994); *United States v. Ramsey*, 785 F.2d 184, 190 (7th Cir. 1986).

The situation before us is somewhat analogous. If Mr. Woodworth is to be believed, and he did not know which lots had actually been sold, it was only because he chose not to know. He knew some lots had been sold and he clearly knew that Abbott had withheld important facts when it failed to answer his inquiry regarding which lots had been sold. (*Id.* at 1967-68, Woodworth.) Yet, rather than pressing his inquiry, he merely shut his eyes and submitted the information he had, delicately phrased so that he could arguably claim disclosure while avoiding direct disclosure of the facts most likely to trigger a rejection from the examiner. After a cursory and shallow inquiry, Mr. Woodworth, like the ostrich, buried his head in the sand – ignorance that he now claims as a reason for failing to make the explicit specific disclosure of a prior sale.

The Federal Circuit has not found such logic convincing, stating that "one should not be able to cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, to merely avoid actual knowledge of that information or prior art. When one does that, the 'should have known' factor becomes operative." *FMC Corp. v. Hennessy Indus., Inc.* 836 F.2d 521, 526 (Fed. Cir. 1987). "Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct, but intent may be inferred from the surrounding circumstances." *Critikon*, 120 F.3d at 1256. "No single factor or combination of factors can be said always to require an inference of intent to mislead . . . ." *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 (Fed. Cir. 1987). However, "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead." *Id.*

Woodworth should have known that the distribution of the sevoflurane in Lot 3298DK might have constituted a prior sale. He avoided that knowledge by failing to insist on an answer to his inquiry. Given his admission that he knew there were sales more than one year prior to the application, that he knew the significance of such sales to the examiner's inquiry, that he considered it important enough to ask for the specific information and to require some sort of disclosure, his failure to insist on an answer to his inquiry is, at the very least, grossly negligent and, most likely, sufficient to infer intent to deceive.

Fortunately for Mr. Woodworth, as pointed out above, this Court has found insufficient evidence to establish that the sale of sevoflurane in Lot 3298DK was a prior sale due to a lack of clear and convincing proof that the sevoflurane in that lot contained sufficient Lewis acid inhibitor to prevent degradation. This means that the materiality of the withheld information is lessened substantially. For that reason and the fact that Woodworth at least disclosed a prior "distribution," the Court, having balanced the level of intent and materiality required to establish inequitable conduct, finds that the evidence fails to support such a finding.

CONCLUSION

For the reasons stated above, the Court finds that Abbott has failed to prove infringement, either literal or under the doctrine of equivalents. The Court further finds that Baxter has failed to prove invalidity, either by anticipation, prior sale or inequitable conduct.

Dated: September 26, 2005

SO ORDERED **ENTER:**

RONALD A. GUZMÁN
District Judge